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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/783,720	02/14/2001	Myles S. Douglas	ENDOLOG.004C2	2203

20995 7590 05/12/2003

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EXAMINER

HO, UYEN T

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 05/12/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)
	09/783,720	DOUGLAS, MYLES S.
	Examiner (Jackie) Tan-Uyen T. Ho	Art Unit 3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 05 March 2003.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) 18-20 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-17 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) Interview Summary (PTO-413) Paper No(s). _____.
5) Notice of Informal Patent Application (PTO-152)
6) Other:

DETAILED ACTION

1. The amendment filed on 3/5/2003 has been fully considered but it does not place the application in condition for allowance.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 1-9, 11-13, 15 and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Robinson et al. (5,860,998).

In regard to claim 1, Robinson et al. disclose a bifurcated vascular graft comprising: a hollow tubular body member (22) having first and second open ends, said second end (27) defining a first opening; a first hollow tubular limb member (16) having

first and second open ends; and a second hollow tubular limb member (18) having first and second open ends wherein the first open end of each of said first and second hollow tubular limb members extend through said first opening of the second end (27) of the hollow tubular body member (22) and are connected to the hollow tubular body member (22) near the first open end of said hollow tubular body member such that a length of said limb members are circumferentially contained within said hollow tubular body member (col. 11, lines 28-47).

In regard to claim 2, Robinson et al. disclose the bifurcated vascular graft of Claim 1 wherein said first and second hollow tubular limb members have approximately equal diameters, said diameters being smaller than a diameter of said hollow tubular body member (figs. 16-20, col. 11, lines 28-47).

In regard to claim 3, Robinson et al. disclose the bifurcated vascular graft of Claim 1 wherein said first and second hollow tubular limb members extend beyond the second end of the hollow tubular body member to a pair of smaller lumens (30' and 28') at the mid section of the hollow tubular body (fig. 21, col. 11, lines 28-47).

In regard to claim 4, Robinson et al. disclose the bifurcated vascular graft of Claim 1 further comprising at least one of a first stent and first structural support (38) located adjacent to the first end of said hollow tubular body member (figs. 17 and 19).

In regard to claim 5, Robinson et al. disclose the bifurcated vascular graft of Claim 4 wherein said at least one of a first stent and first structural support (38) is positioned about an interior portion of said hollow tubular body member (figs. 17, 19 and 21).

In regard to claim 6, Robinson et al. disclose the bifurcated vascular graft of Claim 4 further comprising at least one of a second stent and second structural support (94/16, fig. 16) located adjacent to the second end of said first hollow tubular limb member.

In regard to claim 7, Robinson et al. disclose the bifurcated vascular graft of Claim 6 wherein said at least one of a second stent and second structural support (94/16, fig. 16) is positioned about an exterior of said first hollow tubular limb member.

In regard to claim 8, Robinson et al. disclose the bifurcated vascular graft of Claim 6 further comprising at least one of a third stent and a third structural support (94/18, fig. 16) located adjacent to the second end of said second hollow tubular limb member.

In regard to claim 9, Robinson et al. disclose the bifurcated vascular graft of Claim 8 wherein said at least one of a third stent and third structural support (40, fig. 19) is positioned about an exterior of said first hollow tubular limb member.

In regard to claim 11, Robinson et al. disclose the bifurcated vascular graft of Claim 1 wherein said first and second hollow tubular limb members are attached to one another along a portion of a circumference of their first open ends (although, limb member 16,18 are not interconnected together, limb members 16 and 18 are attached to each other with the lumen of the tubular graft 22).

In regard to claim 12, Robinson et al. disclose the bifurcated vascular graft of Claim 11 wherein at least a portion of the circumference of the first ends of each of said first and second hollow tubular limb members is attached to a portion of a circumference

of the first end of said hollow tubular body member (inherent, attached does not mean interconnected).

In regard to claim 13, Robinson et al. disclose the bifurcated vascular graft of Claim 11 wherein the attachment between the first open ends of the first and second hollow tubular limb members is seamless (fig. 21, col. 11, lines 28-47).

In regard to claim 15, Robinson et al. disclose the bifurcated vascular graft of Claim 11 further comprising: at least one of a first stent and a first structural support (40, fig. 19) located adjacent the first open end of said first hollow tubular body member; at least one of a second stent and a second structural support (94/18) located adjacent the second open end of said first hollow tubular limb member; and at least one of a third stent and a third structural support (94, 18) located adjacent the second open end of said second hollow tubular limb member.

In regard to claim 16, Robinson et al. disclose the bifurcated vascular graft of Claim 15 wherein said at least one of a first stent and first structural support is positioned about an interior of said hollow tubular body member, said at least one of a second stent and second structural support is positioned about an exterior of said first hollow tubular limb member, and said at least one of a third stent and third structural support is positioned about an exterior of said second hollow tubular limb member (figs. 16, 19, 21, col. 11, lines 28-47).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 10, 14 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robinson et al. '998 in view of Cox et al. (5,824,040). Although, Robinson et al. fail to disclose: the bifurcated vascular graft of claim 9 or 16 wherein a portion of the second ends of said first and second hollow tubular limb members are folded back over said at least one of a second stent and second structural support and at least one of a third stent and third structural support, respectively, such that the second ends of said first and second hollow tubular limb members form cuffs; and the bifurcated vascular graft of Claim 11 further comprising a reinforcement suture positioned under the attachment area of the first ends of said first and second hollow tubular limb members, attention is directed to the Cox et al. which teach in figures 1 and 3A-7A stent/structural supports attached to the graft to support each end of the graft or/and through out the graft, wherein the stent can be disposed inside the graft (fig. 6C, col. 13, lines 6-27) or outside the graft (figs. 3A-5H and 7A), reinforcement sutures being used to secure the stent and the graft together (col. 9, lines 39-46) and wherein the end of graft (83) may fold back over the stent to form cuffs (col. 12, line 56 to col. 12, line 26). Therefore, it would have been obvious to one skill in the art at the time the invention was made in view of Cox et

al. to provide the bifurcated vascular graft of Robinson et al. with fold back ends of the graft in order to improve the seal between the ends of the graft and irregular body lumen and reinforcement sutures in order to further secure stent/support structure and the graft together.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to (Jackie) Tan-Uyen T. Ho whose telephone number is (703) 306-3421. The examiner can normally be reached on MULTIFLEX Mon. to Sat..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached on (703) 308-2496. The fax phone

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numbers for the organization where this application or proceeding is assigned are (703) 746-3977 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.


(Jackie) Tan-Uyen T. Ho
Patent Examiner
Art Unit 3731
May 8, 2003


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